



SEP 27 2011

K112371

GE Healthcare
510(k) Premarket Notification Submission

Section 5: 510(k) Summary

LOGIQ P3



SEP 27 2011

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: August 15, 2011

Submitter: GE Healthcare
9900 Innovation Dr
Wauwatosa, WI 53226

Primary Contact Person: Bryan Behn
Regulatory Affairs Manager
GE Healthcare
T:(414)721-4214
F:(414)918-8275

Secondary Contact Person: TC Mohanmurthy
Regulatory Affairs Leader
GE Healthcare
T: +91 80408 95020

Device: Trade Name: LOGIQ P3 Ultrasound System

Common/Usual Name: LOGIQ P3

Classification Names: Class II

Product Code: Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K102256 LOGIQ e
K102104 Vivid P3

Device Description: The subject device consists of a mobile console with keyboard, specialized controls, a color video LCD display with electronic-array transducers. The proposed device is a console based device but predicated is a laptop based device. It is a Track 3 general-purpose imaging and analysis system providing real-time digital acquisition, processing and display capability intended for general radiology imaging and evaluation with some cardiology and vascular applications.

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics, Abdominal (including GYN), Pediatric, Small Organ (including breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (adult and pediatric),



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Peripheral Vascular, Intraoperative (abdominal, thoracic and peripheral), Musculo-skeletal Conventional, Urology (including prostate), Transrectal and Transvaginal.

Technology: The LOGIQ P3 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence: Summary of Non-Clinical Tests:
The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. LOGIQ P3 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final Acceptance Testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P3, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ P3 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W. Innovations Dr
WAUWATOSA WI 53226

SEP 27 2011

Re: K112371

Trade/Device Name: GE LOGIQ P3 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 15, 2011
Received: August 17, 2011

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ P3 Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>4C</u>	<u>3S</u>
<u>E8C</u>	<u>8C</u>
<u>E8Cs</u>	<u>T739</u>
<u>5Cs</u>	<u>6S</u>
<u>8L</u>	<u>3.8CA</u>
<u>11L</u>	<u>7.5LA</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)



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510(k) Number (if known):

Device Name: LOGIQ P3

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/Obstetrics, Abdominal (including GYN), Pediatric, Small Organ (including breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (adult and pediatric), Peripheral Vascular, Intraoperative (abdominal, thoracic and peripheral), Musculo-skeletal Conventional, Urology (including prostate), Transrectal and Transvaginal.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use NA
(Part 21 CFR 801 Subpart C)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and
Safety

510(k) Number

K112371



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ P3 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse*	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	N	N	N	N	N	N	N	N	N		
Abdominal ^[1]	N	N	N	N	N	N	N	N	N		
Pediatric	N	N	N	N	N	N	N	N	N		
Small Organ ^[2]	N	N	N		N	N	N	N	N		
Neonatal Cephalic	N	N	N	N	N	N	N	N	N		
Adult Cephalic	N	N	N	N	N	N	N	N	N		
Cardiac ^[3]	N	N	N	N	N	N	N	N	N		
Peripheral Vascular	N	N	N		N	N	N	N	N		
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N		
Musculo-skeletal Superficial											
Other ^[4]	N	N		N	N	N	N	N	N		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	N	N	N		N		N	N	N		
Transvaginal	N	N	N		N		N	N	N		
Transurethral											
Intraoperative ^[5]	N	N	N		N	N	N	N	N		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics and B-flow.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)

Mary Speth
(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety



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510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 4C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P		
Abdominal ^[1]	P	P	P		P	P	P	P	P		
Pediatric	P	P	P		P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

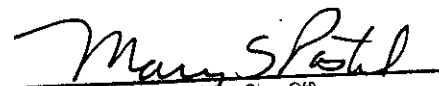
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[†] Coded Pulse is for digitally encoded harmonics and B-flow.

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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with E8C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P		P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

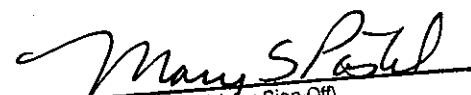
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 510K K112371



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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with E8Cs Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P		P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

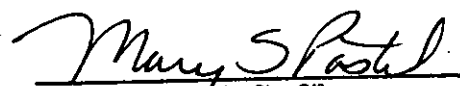
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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 5Cs Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	P	P	P		P	P	P	P	P		
Abdominal ^[1]	P	P	P		P	P	P	P	P		
Pediatric	P	P	P		P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P		P	P	P	P	P		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate


[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 8L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P	P	P	P	P		
Pediatric	P	P	P		P	P	P	P	P		
Small Organ ^[2]	P	P	P		P	P	P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]	P	P	P		P	P	P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

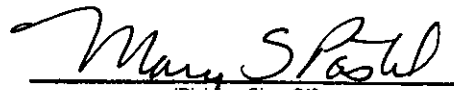
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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 11L Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P	P	P	P	P		
Pediatric	P	P	P		P	P	P	P	P		
Small Organ ^[2]	P	P	P		P	P	P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative	P	P	P		P	P	P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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Notes: [1] Abdominal includes renal, GYN/Pelvic

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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 3S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac ^[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
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Transvaginal											
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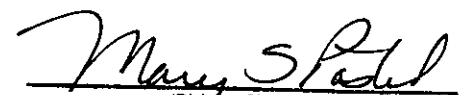
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)


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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 8C Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P	P	P	P	P		
Pediatric	P	P	P		P	P	P	P	P		
Small Organ ^[2]	P	P	P		P	P	P	P	P		
Neonatal Cephalic	P	P	P		P	P	P	P	P		
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

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Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

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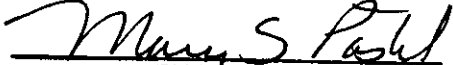
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription User (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety
 510K K112371



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with T739 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Small Organ ^[2]	P	P	P		P	P	P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P	P	P	P	P		
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P		
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5]	P	P	P		P	P	P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).

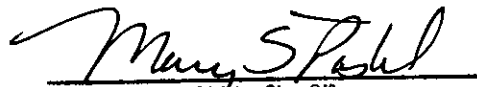
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics and B-flow.

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GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 6S Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P	P	P	P	P	P	P		
Pediatric	P	P	P	P	P	P	P	P	P		
Small Organ ^[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P		
Adult Cephalic	P	P	P	P	P	P	P	P	P		
Cardiac ^[3]	P	P	P	P	P	P	P	P	P		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

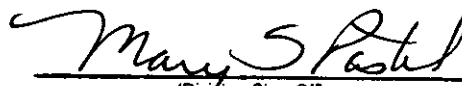
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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510K 15112371



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 3.8CA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics	N	N	N		N	N	N	N	N		
Abdominal ^[1]	N	N	N		N	N	N	N	N		
Pediatric	N	N	N		N	N	N	N	N		
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	N	N	N		N	N	N	N	N		
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

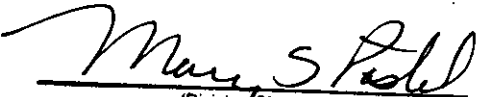
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics and B-flow.

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510K K112371



GE Healthcare
510(k) Premarket Notification Submission

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P3 with 7.5LA Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other (Notes)
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	N	N	N		N	N	N	N	N		
Pediatric	N	N	N		N	N	N	N	N		
Small Organ ^[2]	N	N	N		N	N	N	N	N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	N	N	N		N	N	N	N	N		
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N		
Musculo-skeletal Superficial											
Other ^[4]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative	N	N	N		N	N	N	N	N		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes renal, GYN/Pelvic

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics and B-flow.

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